Rationale

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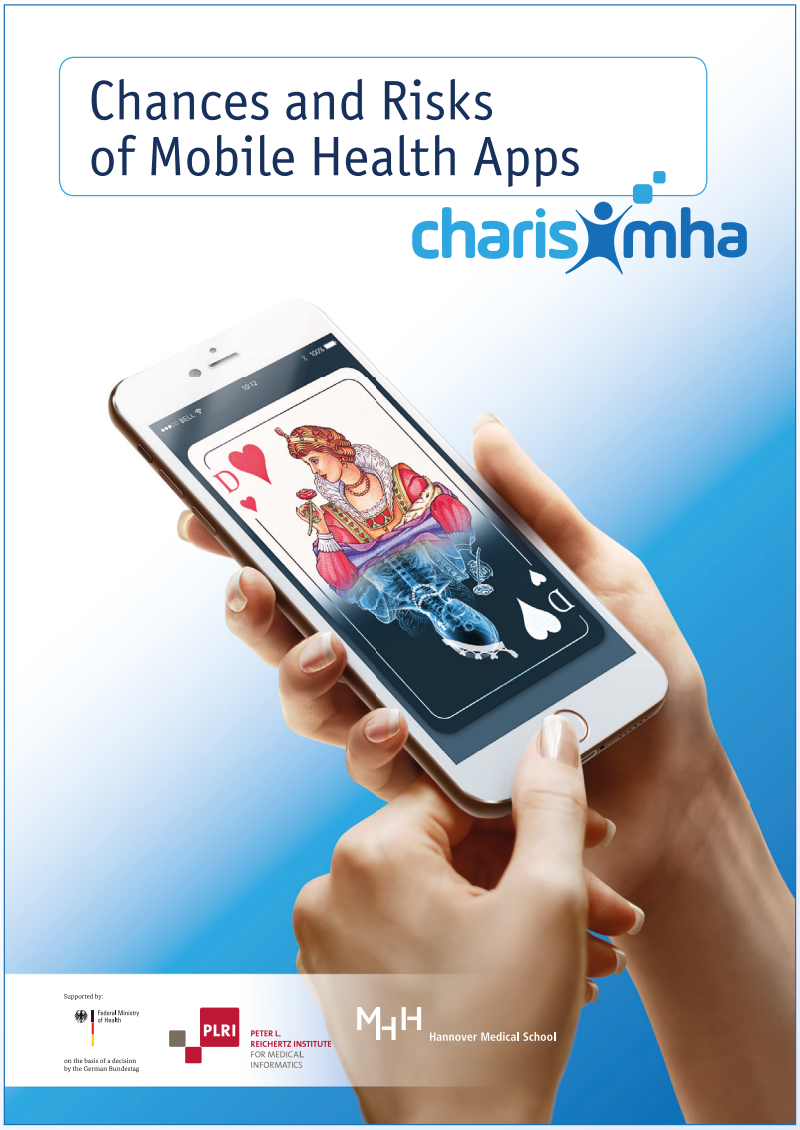

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1 Introduction

In 1991, Mark Weiser predicted that the technology that most influences us is the technology that disappears before our eyes and weaves itself completely into our everyday lives (Weiser 1991). Almost a quarter of a century later, we already rely on such developments on a daily basis: smartphones, tablets, smart watches and data glasses; what is on offer is growing with the miniaturisation of technology. Basically, these devices are high-performance computers "en miniature" and they are either incorporated into, or even created as, everyday objects. The market is not only growing for these devices, but also for the software with which they operate. Increasingly, platforms are being created whereby third parties can provide their own computer programs which are commonly referred to as "apps".

Mobile devices and apps are also finding their way into the health sector. "mHealth" (mobile health) is integrated into a wide range of health services which are offered on portable mobile devices. Health apps on smartphones and tablets are the most popular type of application in this field. There are numerous possibilities for using health-related apps and they range from comparatively simple fitness and wellness apps to applications providing sophisticated diagnostics and treatment options. The target audience is as diverse as the range of applications being offered: relevant apps are used not only by patients and insurance companies, but also by healthcare professionals. Health apps already play an important role in the secondary healthcare market, but are also gaining importance for the primary healthcare market, where patient services are reimbursed through statutory (GKV) and private health insurance (PKV).

Overall, various economic and political stakeholders, as well as users – on a national and international level – see great potential for this new technology for healthcare accompanied by growth in the digital economy. Hopes of improving healthcare through cost-effective measures are to be met by implementing mHealth (Becker et al. 2014). A possible starting point can be measures in the context of prevention, which provide a cost-effective means for promoting self-help and patient autonomy (Landry 2015, Boulos 2011). As a consequence of the recently adopted Prevention Act, in Germany, support for health related self-help has been increased, which also promotes the discussion about mHealth based solutions.

The optimisation of care for chronically ill patients is also being identified as a possibly effective field of application. In particular, potential for success is seen for treatment monitoring models and measures to improve adherence to treatment (Becker et al. 2012). The same applies to post-operative care and rehabilitation. For structurally weak regions with only few health care professionals, digital solutions may offer support for providing or receiving care, independent of location (Anderson, Henner and Burkey 2013). On the whole, mHealth has the potential to improve patients'/insured people's health literacy which may allow them to exercise their patient rights more easily.

However, new apps can also confuse users, fail to provide correct information or may create a false sense of security. So far, risks have only been insufficiently studied. Knowledge of hazards and health risks is, however, essential for weighing up the risks against the benefits. Regarding this latter point, medico-ethical considerations are also to be taken into account, and these deal with issues of autonomy, participation, privacy and monitoring in the context of the use of health apps.

2 Problem Definition

The rapid and enthusiastically greeted spread of mobile technologies in medicine has so far resulted in a proliferation of methods. Many projects are geared to short-term successes and have so far been done without a long-term strategic orientation. This multifaceted complexity for everyone involved makes it difficult to assess the opportunities and risks, particularly because a solid base of information is currently lacking (Albrecht

2013, Nurul and Albrecht 2014). The lack of extensive scientific evidence regarding the long-term benefits of mobile solutions in the above fields is often criticised (van Heerden, Tomlinson and Swartz 2012). Existing studies greatly vary in terms of both methods and content, making a comparison of the results as well as their transferability to other situations (Free et al. 2013, Free et al. 2013a) and possible reimbursement of costs more difficult. The new opportunities arising from the technology may equally be underestimated or overestimated. Measures which are based on an insufficiently valid foundation run the risk of the available control mechanisms being inadequately aligned. This can adversely affect care (beyond the needs), security (measures that are too relaxed) or can hamper innovation (measures that are too strict).

Creating a base of evidence may help reduce the barriers for adopting new legislation and facilitate the necessary interdisciplinary cooperation, ultimately improving the quality of patient care. The current lack of a base of evidence on the subject of mHealth is a global problem. There are only few independent studies, and often, available personnel capacities are insufficient for meeting the demand for scientifically sound analysis. This results in a lack of orientation, which, amongst other things, leads to insufficiently adapted legal requirements for new mHealth technology and thus complicates or misdirects innovations. This also has an impact on Germany as a business location. A market research firm advises, for example, that mHealth products should only be developed for the German market with low priority (research2guidance 2015), in part because electronic prescriptions are not possible, there is a lack of infrastructure for electronic health records, and professional laws only allow for remote care in a limited set of circumstances.

3 Objective

The aim of the project "Chances and Risks of Mobile Health Apps (CHARISMHA)" was to take stock of the current framework for the use of health apps in Germany in the context of efforts made by other EU countries. The objective was to identify fields of action for promoting meaningful use and recommend measures to minimise risks. The exploration of the field needed to include a variety of disciplines (e.g. medicine, economics, law, ethics, see below). Existing regulations, which are usually not specifically adapted to the requirements of mobile technologies, had to be examined via a multidisciplinary approach with regard to their strengths, weaknesses, opportunities and risks. Using input from various disciplines, potential solutions needed to be developed, and these are intended to serve as a basis for adapting the legal frameworks and initiating targeted funding programmes as well as incentive schemes.

4 Method

The study[1] was based on a catalogue of key subjects and questions, which was derived from the general discussion on the topic and supplemented with suggestions from the Federal Ministry of Health (BMG). Answering these questions required a broad, flexible and interdisciplinary approach, not least of all due to the rapid, scarcely regulated developments, as well as overwhelming and yet confusing media coverage. Various interfaces and intersections between the different specialist disciplines had to be taken into account in order to uncover and understand the complex dynamics and synergisms/constraints of the existing complex relationships. The work was carried out by an interdisciplinary team of experts.

Each expert worked independently on the particular aspects relating to her or his discipline and used the scientific methods such as structured literature reviews and other tools. The respective partial results, also containing initial conclusions and recommendations in addition to the analysis, were immediately made available to all team members. In five coordination workshops, existing results were presented and comprehensively discussed in order to adequately consider the relevant interfaces and to close any gaps in the content. Smaller teams were formed to work intensively on specific overarching issues. Conclusions and recommendations were jointly discussed and coordinated.

The results were summarised in a preliminary final report and made available to various stakeholders with an invitation to comment within four weeks. At the beginning of the project, the representatives were invited and informed about the planned stock taking and were invited to participate in the comment phase of the project. The feedback was collected and its relevance to the report was jointly evaluated by the experts, with

[1] Chronological sequence: the study period spanned eight months, beginning on 15/08/2015 and ending on 15/04/2016. The study was drawn up 03/02/2016 and released for the four-week comment period, beginning on 08/03/2016. A total of five consultation workshops were held at four-weekly intervals. The final report was finalised on 15/04/2016 after processing the feedback.

errors corrected in the report and relevant aspects being included in the conclusions. Lastly, the report was finalised and published as a result. Available comments on the study are provided on the project's website (http://www.charismha.de/).

5 Financing

The study was funded by the German Federal Ministry of Health (BMG) under the grant number ZMV I 1 - 2515FSB503. The total amount was EUR 103,690.30, which takes into account the own contribution of the Medizinische Hochschule Hannover (Hannover Medical School).

6 Structure

The results are presented in a chapter structure as explained below.

The first section (Chapter 1, "Introduction and Definition of Terms") first establishes the subject of electronically supported health (eHealth) and the contribution made by mobile technology (mHealth) in this context. Then, the multifaceted concept of health apps is set out, taking into account the underlying technology and the stakeholders involved (manufacturers, users). The following section provides a description of the market (Chapter 2, "Health Apps and Market"). Policy frameworks are described in Chapter 3 ("Health Apps and Political Framework"). Chapter 4 analyses general challenges arising from the use of this technology with regard to care, with a special focus on the challenges arising from the use of apps in (rural) care settings and from the requirements of specific user groups with special needs, such as the chronically ill (Chapter 4, "Health Apps and Challenges"). In the subsequent chapters, the greatest potentials for individual fields of application in the context of prevention (Chapter 5, "Health Apps and Prevention"), diagnostics and treatment (Chapter 6, "Health Apps and Diagnostics and Treatment"), as well as (healthcare) research (Chapter 7, "Health Apps in the Context of Research") are worked out in detail. After describing the opportunities arising from the use of health apps, the risks are considered in Chapter 8 ("Health Apps and Risks"). Here, in addition to discussing the concepts of damage, hazards and risks, risks arising from the use of apps in a medical context are considered and assessed for all user groups (the health-conscious, patients, professional users). Ethical aspects users and manufacturers are confronted with are described in Chapter 9 ("Health Apps and Ethics").

The subsequent chapters describe the legal frameworks in relation to the demands of data protection and liability (Chapter 10, "Health Apps and Data Protection"), as well as regulatory requirements and legal provisions (Chapter 11, "Health Apps as Medical Devices").

In particular, statutory health insurance companies operate in a very rigid legal framework and must comply with multiple regulations in order to guarantee healthcare. To manufacturers of health apps, this market is very appealing. Offers that are reimbursed/funded by insurers benefit those who are insured. Therefore, a separate chapter is devoted to the analysis of the market situation, the reimbursement possibilities and the effects and incentives for statutory and private health insurance: Chapter 12 ("Health Apps in Statutory and Private Health Insurance") tackles the evaluation and analysis of health apps offered by private and statutory health insurance. The specifics to be considered in this context, as well as the presentation of reimbursement methods of apps by the payers are looked at in particular here.

Due to the low prerequisites for developing health apps and the low thresholds for access to the market through simple cross-border sales processes, users are confronted with a highly dynamic and scarcely regulated market situation. In the subsequent chapters, guidance for patients/insured persons (Chapter 13, "Orientation for Users of Health Apps") and professional users (Chapter 14, "Orientation for Professional Users of Health Apps"), as well as for manufacturers (Chapter 15, "Orientation for Manufacturers of Health Apps") is compiled, taking into account the insights gained previously.

Sections of each chapter contain conclusions naming possible fields of action for policymakers and stakeholders in the health care sector and highlight options for actions and recommendations for further actions based on the findings for the respective topics.

7 Summary

The presented work is meant to provide insights into current developments and trends with respect to the use of mobile health apps. A special emphasis shall be placed on the areas of prevention, diagnostics and therapy as well as healthcare in general, for example regarding the care for patients with chronic conditions,

elderly people or rural populations. Other important areas of interest are the identification of risks that may arise from using health apps, especially in the context of data protection and data security. An appraisal of the practical, as well as regulatory hurdles one may encounter when using health-related apps in various use cases is given along with a description of points where adaptations to existing regulations might be advised. In addition, the ethical implications of using health-related apps in various contexts are outlined. In order to better respond to the needs of individual stakeholders, i.e. patients as well as medical professionals and developers of health apps, an outline of possible ways to support each of these groups is provided. Finally, the closing summary chapter describes important areas where action may be advised to be able to eliminate the identified hurdles, which may be technical in nature, but may also be due to legal or ethical concerns. This aims at minimising potential risks for all those who are dealing with health related apps, but may also serve to provide insights into how relevant uses of mobile technologies in health contexts can be promoted.

8 Literature

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